

What is claimed is:

1. A hand-held assay device for measuring the presence of a sample selected from the group consisting of ATP and other entity capable of generating chemiluminescence, comprising:

a first light sensor generating a sample signal in response to detecting the chemiluminescence;

a second light sensor shielded from the chemiluminescence and generating a reference signal; and

a controller receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals.

2. The hand-held assay device defined in claim 1, wherein the first and second light sensors are photodiodes, the hand-held device further comprising sample and reference switched integrators, each connected in series with the respective one of the photodiodes and outputting integrated values of the sample and reference signals received by the controller, the reference signal being generated in response to environmental changes selected from the group consisting of temperature, humidity, external shocks and a combination thereof.

3. The hand-held assay device defined in claim 2, wherein each of the integrators is provided with a respective integration bypass capacitor and a solid state switch connected in parallel to one another to provide the integrated values of the sample signal and the reference signal.

4. The hand-held assay device defined in claim 1 wherein the controller is a microprocessor having a memory which stores a sample threshold value, the hand-held device further comprising software executing on the microprocessor for closing the solid state switches for a controllable integration time to provide the integrated values of the sample and reference

signals corresponding to the duration of the closed state of the solid state switches, and software for comparing a value representing the resulting signal to the sample threshold value to determine the sample if the resulting signal is at least equal to the sample threshold value.

5. The hand-held assay device defined in claim 4, further comprising software executed on the controller for incrementally increasing the integration time if the resulting signal is less than the sample threshold value.

6. The hand-held assay device defined in claim 5, further comprising software executed on the controller for completing the determination of the sample upon reaching a predetermined integration time limit stored in the memory, and software executed on the controller for detecting negative saturation of the switched integrator due to a rapid environmental change and for setting an integration time limit shorter than the predetermined time limit.

7. The hand-held assay device defined in claim 1, further comprising a pair of analog to digital converters digitizing the sample and reference signals, respectively, and software executed on the controller for subtracting the digitized reference signal from the digitized sample signal.

8. The hand-held assay device defined in claim 1, further comprising software executed on the controller for calculating a logarithmic number of the resulting signal and a display for displaying the calculated logarithmic number if calculated resulting signal exceeds the threshold value.

9. The hand-held assay device defined in claim 1, further comprising an LED turned on in response to powering up the device to emit a beam of light extending along a path, a transparent window along the path between the LED and the first light sensor, the controller having a calibration mode, wherein the cleanliness of the window is controlled in response to a signal generated by the first light sensor which is struck by the beam from the LED.

10. The hand-held assay device defined in claim 9, further comprising software executed on the controller for turning the LED on in response to powering up of the hand-held device, software executed on controller for measuring the signal representing light intensity of the light beam penetrating through the transparent window, and a comparator for providing a calibration value if the measured signal is within an expected intensity range of an LED reference signal stored in the memory.

11. The hand-held assay device defined in claim 10, further comprising software executed on the controller for adjusting the resulting signal indicative of the sample presence for the calibration value.

12. The hand-held assay device defined in claim 1, further comprising a sample compartment having the transparent window upstream from the first light sensor and a door spaced from the window, the consumable, which has been used to swipe a surface to collect the sample to be tested, being removably inserted through the door into the sample compartment to bring the sample towards the window.

13. The hand-held assay device defined in claim 12 wherein the LED is pressed in a peripheral wall of the sample compartment and spaced from the transparent window.

14. The hand-held assay device defined in claim 12 wherein the consumable is positioned in the sample compartment to block the beam of light emitted by the LED, the device further comprising software executed on the controller for preventing the device from operating in response to a signal indicative of the open door.

15. The hand-held assay device defined in claim 1, wherein the controller has a consumable-detection mode, wherein software is executed on the controller for detecting whether a signal inputted in the controller is within a

predetermined range of intensity, which has low, mid and high levels and for determining if this signal is indicative of the presence of the consumable in the sample compartment.

16. The hand-held assay device defined in claim 15, further comprising software executed on the controller for turning the LED on, and software executed on the microprocessor for outputting an integrating value of the signal indicative of the presence of the consumable if the integrating value is at least equal to the high level exceeding NL_{exp} , wherein L_{exp} is the stored LED reference value and N is a predetermined integer.

17. The hand-held assay device defined in claim 15, further comprising software executed on the controller for turning the LED off if the value of the signal inputted in the controller has been determined to be at least equal to the mid-level but less than the high level of the predetermined range with the LED on, wherein the mid-level corresponds to the stored LED reference value, software executed on the controller for determining a new integrated value of the signal detected in response to turning the LED off, and software executed on the controller for comparing the integrated values L1 and L2 with the LED on and the LED off, respectively, to display the signal indicative of the presence of the consumable if these integrated values are substantially the same.

18. The hand-held assay device defined in claim 15, further comprising software executed on the controller for comparing the signal inputted in the controller with the LED off to the low level of the predetermined range and displaying a warning signal indicative of the absence of the consumable if the integrated value of the inputted signal is below the low level.

19. The hand-held assay device defined in claim 15, further comprising software executed on the controller for turning the LED off, said signal being indicative of the presence of the consumable in response to determining an

integrated value of the signal if the determined value is at least equal to the mid-level of the predetermined range.

20. The hand-held assay device defined in claim 19, further comprising software executed on the controller for determining whether the signal is at least equal to the low level of the predetermined range, software executed on the controller for turning the LED on in response to detection of the low level, software executed on the controller for determining an integrated value of the signal after the LED has been turned on, and software for comparing the values of the resulting signal with the LED off and on, respectively, to display the signal indicative of the presence of the consumable if the determined values are substantially the same.

21. The hand-held assay device defined in claim 1, further comprising software executed on the controller for measuring first and second values of a signal processed by the controller with the LED on and off, respectively, software for subtracting second value from the first value, and software for outputting the signal indicative of the absence of the consumable if the difference is between a high-level and a low level of the predetermined range stored in the memory.

22. The hand-held assay device defined in claim 2, further comprising software executed on the controller for closing/opening the solid state switches before determining the resulting signal indicative of the sample presence to short the integration feedback capacitors for discharging accumulated photodiode charge.

23. The hand-held assay device defined in claim 10 wherein the transparent window is made from glass.

24. The hand-held assay device defined in claim 23 wherein one of the opposite sides of the window is coated with a coating of an optically

transparent, conductive material to minimize the direct injection of charge during introduction of the sample into the sample compartment.

25. The hand-held assay device defined in claim 24 wherein the coating is indium tin-oxide (ITO) placed on the side of the window, which faces away from the first photodiode, to form with a chassis of the hand-held device a discharging element acting as a Faraday cage, the opposite side of the window being covered with a filter to limit the light striking the first photodiode.

26. The hand-held assay device defined in claim 23 wherein the window is made from a colored glass to serve as a filter selected from the group consisting of a band pass filter, band-limited filter and combination of these.

27. The hand-held assay device defined in claim 24 wherein the coating is placed on a side of the window facing the first photodiode, whereas the other side of the window is covered with a filter.

28. The hand-held device defined in claim 12 wherein the transparent window is spaced from the bottom of the consumable, which is made of conductive plastic, the hand held device further comprising an optic including a pair of plano-convex lens between the consumable and the transparent window.

29. The hand-held device defined in claim 12 further comprising software executed on the controller for determining the presence of holes in the door and for generating a warning signal in response to the detection of the holes.

30. A hand-held assay device for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, comprising:

- a housing provided with a sample compartment;
- a detection assembly in the housing for detecting the

chemiluminescence and generating a signal in response to its detection;

a transparent window between the sample chamber and detection assembly, said transparent window being covered with a conductive transparent coating to minimize the direct injection of static charge; and

a controller determining whether a resulting signal processed in response to the signal generated by the detection assembly is indicative of the presence of the sample.

31. The hand-held assay device defined in claim 30 further comprising a chassis made of a conductive material and in contact with the coating to act as a Faraday cage.

32. The hand-held assay device defined in claim 30 wherein the conductive coating is indium tin-oxide (ITO).

33. The hand-held assay device defined in claim 30 wherein the detection assembly comprises:

a first photodiode generating a sample signal in response to chemiluminescence;

a second photodiode shielded from the chemiluminescence and generating a reference signal;

sample and reference switched integrators, each connected in series with the respective one of the first and second photodiodes and outputting integrated values of the sample and reference signals received by the controller, the reference signal being generated in response to environmental changes selected from the group consisting of temperature, humidity and a combination thereof, and

software executed on the controller for subtracting the integrated value of the sample signal from the integrated value of the sample signal to determine the resulting signal.

34. The hand-held assay device defined in claim 30 wherein the transparent window has opposite sides, one of which is coated with the ITO providing a shutterless structure of the hand-held device, whereas the other side of the transparent window has a bandpass filter selected from the group consisting of a coating and a whole body.

35. The hand-held assay device defined in claim 30 wherein the first photodiode is juxtaposed with the side of the transparent window provided with the bandpass filter.

36. The hand-held assay device defined in claim 30, further comprising an LED mounted in the sample compartment to emit a beam of light projecting through the window and striking the first photodiode which generates a signal, and software executed on the controller for comparing the signal generated by the first diode to an LED reference value to provide a calibration value indicative of the cleanliness of the transparent window and accounted for during the measurement of the resulting signal.

37. The hand-held assay device defined in claim 30, further comprising a consumable removably inserted in the sample compartment after collecting the sample, and software executed on the controller for detecting the presence of the consumable in the sample compartment.

38. The hand-held assay device defined in claim 33 wherein each of the integrators is provided with a respective integration bypass capacitor and a solid state switch connected in parallel to one another to provide the integrated values of the sample signal and the reference signal, the hand-held device further comprising software executed on the controller for opening/closing the solid state switches before measuring the resulting signal to discharge accumulated static charges.

39. A hand-held assay device for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, comprising:

- a housing provided with a sample compartment receiving the sample;
- a source of light mounted in the housing and emitting a beam of light extending along a path;
- a detection assembly along the path for generating a resulting signal in response to the chemiluminescence;
- a transparent window along the path between the sample chamber and the detection assembly, the detection assembly generating a calibration signal indicating cleanliness of the transparent window in response to being struck by the beam of light from the source; and
- a controller having an analytical mode, wherein the resulting signal is evaluated, and a calibration mode, wherein the calibration signal is evaluated.

40. The hand-held assay device defined in claim 39 wherein the detection assembly comprises:

- a first photodiode generating a sample signal in response to chemiluminescence;
- a second photodiode shielded from the chemiluminescence and generating a reference signal;
- sample and reference switched integrators, each connected to the respective one of the first and second photodiodes and outputting integrated values of the sample and reference signals received by the controller, the reference signal being generated in response to environmental changes selected from the group consisting of temperature, humidity and a combination thereof,
- software executed on the controller in the analytical mode for subtracting the integrated value of the sample signal from the value of the sample signal to determine an integrating value of the resulting signal, and
- software executed on the controller for comparing the integrating value of the resulting signal to a sample threshold and for outputting the integrating

value of the resulting signal if the value of the resulting signal is at least equal to the sample threshold.

41. The hand-held assay device defined in claim 39 wherein the source of light is an LED pressed in a peripheral wall of the sample compartment, said controller being provided with software for comparing the measured calibration signal with a reference calibration signal and displaying an error signal if the measured calibration signal is not within the expected range of the reference calibration signal.

42. The hand-held device defined in claim 40, further comprising software executed on the controller for adjusting the resulting signal for the calibration signal if the latter is being within the expected range of the reference calibration signal.

43. A hand-held assay device for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, comprising:

- a housing provided with a sample compartment;
- a consumable collecting the sample and removably inserted into the sample compartment;
- a detection assembly located in the housing along the path and juxtaposed with the consumable upon insertion of the consumable into the sample compartment, the detection assembly generating a resulting signal in response to the chemiluminescence and generating a consumable-present signal in response to detecting the consumable; and
- a controller having an analytical mode, wherein the resulting signal is evaluated, and a detection mode, wherein the consumable-present signal is evaluated.

44. The hand-held device defined in claim 42, further comprising software executed on the controller for comparing the resulting signal with a

predetermined threshold and for outputting a signal indicative of the presence of the sample if the resulting signal is at least equal to the predetermined threshold.

45. The hand-held assay device defined in claim 42 wherein the detection assembly comprises:

a first photodiode generating a sample signal in response to the chemiluminescence;

a second photodiode shielded from the chemiluminescence and generating a reference signal;

sample and reference switched integrators, each connected to the respective one of the first and second photodiodes and outputting integrated values of the sample and reference signals received by the controller, the reference signal being generated in response to environmental changes selected from the group consisting of temperature, humidity and a combination thereof.

46. The hand-held assay device defined in claim 42, further comprising a source of light mounted in the sample compartment, and software executed on the controller for comparing the consumable-present signal with high, mid and low level values of an expected intensity of the light from the source of light.

47. The hand-held device defined in claim 45, further comprising software executed on the controller in the detection mode for turning the source of light on and software for determining a signal generated by the detection assembly in response to the turning the source of light off.

48. The hand-held device defined in claim 46, further comprising software executed on the controller for turning the source of light on and for determining a signal generated by the detection assembly in response to turning the source of light on, software executed on the controller for

subtracting the determined signal with the source of light off from the determined signal of the source of light off to calculate the difference between the determined signals.

49. The hand-held device defined in claim 47, further comprising software executed on the controller for outputting a signal indicative of the absence of the consumable in the sample compartment if the difference between the determined signals is within a predetermined range having a low level and a high level, wherein the low level corresponds to the reference signal generated by the second photodiode, and the high level correspond to a signal representing the expected intensity of the source of light.

50. A hand-held assay device for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, comprising:

- a housing provided with a sample compartment;
- a consumable adapted to be removably inserted in the sample compartment after collecting the sample, the sample compartment being provided with a transparent bottom;
- a source of light provided in the sample compartment and emitting a beam of light which projects through the transparent bottom;
- a detection assembly juxtaposed with the transparent bottom for generating a first signal in response to detection of the chemiluminescence and a second signal in response to being struck by the beam of light; and
- a controller receiving the first and second signals and having a first mode, wherein the first signal is evaluated to determined the presence of the sample, a second mode, wherein the second signal is evaluated to determine the cleanliness of the transparent bottom, and a third mode, wherein the second signal is determined to be indicative of the presence of the consumable.

51. The hand-held device defined in claim 49 wherein the detection assembly comprises:

a first photodiode generating a sample signal in response to the detection of the chemiluminescence;

a second photodiode shielded from the chemiluminescence and generating a reference signal;

sample and reference switched integrators, each connected to the respective one of the first and second photodiodes and outputting integrated values of the sample and reference signals received by the controller, the reference signal being generated in response to environmental changes selected from the group consisting of temperature, humidity and a combination thereof.

52. The hand-held device defined in claim 49, further comprising software executed on the controller in the first mode for subtracting the integrated value of the reference signal from the integrating value of the sample signal to determine a value of the first signal, and software executed on the controller for comparing the value of the first signal to a predetermined threshold to output a signal indicative of the presence of the sample if the value of the first signal is at least equal to the predetermined threshold.

53. The hand-held device defined in claim 49 further comprising software executed on the controller working in the second mode for turning the source of light, and software executed on the controller for comparing the second signal with a reference signal representing the expected intensity of the source of light, and software executed on the controller for displaying a warning signal if the second signal is beyond the expected intensity range of the source of light.

54. The hand-held device defined in claim 52 wherein the expected intensity range of the source of light having low and high levels, the hand-held device further comprising software executed on the controller for comparing

the second signal with the high level to detect the presence of the consumable if the second signal exceeds the high intensity level at a predetermined value, and software for switching the controller from the third mode to the first mode in response to the detection of the consumable.

55. The hand-held device defined in claim 52 the hand-held device further comprising software executed on the controller for switching the controller from the third mode to the first mode if the second signal is above the high intensity level at a predetermined value to indicate the presence of the consumable in the sample compartment.

56. The hand-held assay device defined in claim 49 wherein the transparent bottom having opposite sides, one of which is coated with an ITO to provide a shutterless structure of the hand-held device.

57. A method of measuring the presence of a sample selected from the group consisting of ATP and other entity capable of generating chemiluminescence, comprising the steps of:

providing a first photodiode for generating a sample signal in response to detecting the chemiluminescence;

providing a second photodiode shielded from the chemiluminescence for generating a reference signal;

providing a controller receiving the sample and reference signal for subtracting the reference signal from the sample signal to determine a resulting signal; and

comparing the resulting signal with a predetermined threshold; and displaying the resulting signal indicative of the sample if the resulting signal is at least equal to the threshold value.

58. A method for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, comprising the steps of:

providing a housing having a sample compartment formed with a transparent bottom;

detecting the chemiluminescence and generating a signal in response to the detection;

providing a film of a conductive plastic material on the transparent bottom, thereby minimizing the direct injection of static charge; and

comparing the signal with a predetermined threshold; and

displaying a value of the signal if the signal is at least equal to the predetermined threshold.

59. A method for detecting the presence of a sample selected from the group consisting of ATP and other entity capable of chemically reacting to generate chemiluminescence, said sample being placed in a sample compartment provided in a housing, comprising the steps of:

generating a sample signal in response to detecting the chemiluminescence;

generating a reference signal in response to detecting environmental changes selected from the group consisting of humidity, temperatures drifts and a combination thereof;

integrating the sample and reference signals during a controllable integration period to produce integrated values of the sample and reference signals;

digitizing the integrated values of the sample and reference signals;

subtracting the digitized value of the reference signal from the digitized value of the sample signal to determine a value of a resulting signal;

comparing the value of the resulting signal with a predetermined threshold and displaying the resulting signal indicative of the presence of the sample if the value of the resulting signal is at least equal to the threshold.

60. The method defined in claim 57 further comprising the step of incrementally increasing the integration time if the resulting signal is less than the threshold, and of monitoring the integration time to prevent further

detection of the sample and reference signals if the integration time has reached a predetermined limit.

61. The method defined in claim 57, further comprising the step of detecting a consumable containing the sample in the sample compartment, sample compartment being provided with a transparent bottom.

62. The method defined in claim 59, further comprising the step of determining the cleanliness of the transparent bottom before determining the resulting signal.